

To: Yamada, Richard (Yujiro)[yamada.richard@epa.gov]
From: Beck, Nancy
Sent: Fri 6/23/2017 3:36:02 PM
Subject: RE: Denka notes and follow-up (email contains deliberative process)

Sounds good.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

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From: Yamada, Richard (Yujiro)
Sent: Friday, June 23, 2017 9:50 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Denka notes and follow-up (email contains deliberative process)

Hey Nancy – happy to call you this afternoon, I will aim for ~1:30 or so – thanks again, Richard

From: Beck, Nancy
Sent: Thursday, June 22, 2017 5:43 PM
To: Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Subject: RE: Denka notes and follow-up (email contains deliberative process)

Happy to chat—it will take a bit of memory jogging to recall anything about the assessment but I'm happy to try.

Maybe catch up tomorrow afternoon? Its usually very quiet on Fridays. And hopefully TSCA press will calm down.

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From: Yamada, Richard (Yujiro)

Sent: Thursday, June 22, 2017 3:59 PM

To: Beck, Nancy <Beck.Nancy@epa.gov>

Subject: FW: Denka notes and follow-up (email contains deliberative process)

Hey Nancy,

Know you are busy, but as an FYI I requested a chloroprene briefing ahead of the Denka meeting – John Vandenberg and Bruce will come to the meeting next Weds in Reagan Bldg. We should talk ahead of meeting to get your take – I know there is an ask here so I wanted to be careful what we say. Thanks much, you must be so relieved from all your efforts these past few weeks!

Richard

From: Gwinn, Maureen

Sent: Thursday, June 22, 2017 3:52 PM

To: Kavlock, Robert <Kavlock.Robert@epa.gov>; Vandenberg, John

<Vandenberg.John@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Yamada, Richard

(Yujiro) <yamada.richard@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Cc: Plotkin, Viktoriya <Plotkin.Viktoriya@epa.gov>; Sjogren, Mya <Sjogren.Mya@epa.gov>;
Branch, Danielle <branch.danielle@epa.gov>; Gentry, Nathan <Gentry.Nathan@epa.gov>;
D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: Denka notes and follow-up

Some notes and follow-up on the meeting we just had. Please feel free to add anything that I may have missed.

Nathan –

I think the first key follow-up will be to update the invitation on Richard's calendar (6/18 at 5pm) to include Bruce and John, include a room here on our 4th floor and VTC to John in RTP and to share with him information on how the Denka folks are getting in to the building etc.

Thanks - Maureen

Ex. 5 - Deliberative Process

not ORD.

7. BK – any health surveillance in the community? Some – LA tumor registry has done some work, but the Parish is pretty big – so most people don't live near this plant. Seems to be an elevated cancer risk if you look by zip code.

8. Modeling based on animal studies.

9. Epi studies good for hazard id but not sufficient for modeling/dose-response

10. RY – which animals and what levels of exposure?

a. **Will follow up on this with materials (IRIS Summary, WOE - https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1021)**

b. BR – mutagenic based on structure – Mutagenic MOA – like 1,3-butadiene. Double bonds – can be broken then reconnect and damage DNA

11. Some of the new studies looked at since 2010 – discuss mutagenicity

12. Discussion of evaluation of evidence – dose-response and PBPK modeling lacking in some ways – written up and shared internally and with one DoJ reviewer.

13. Where are we now? Denka reps have asked about what IRIS would do about the data, or request for correction – IRIS review did not demonstrate the need to do an update based on the new literature.

a. Possibly as part of the update? But in the context of other priorities? Or wait for the response from the RfC panel.

14. Request for Correction process – panel of three AA-level members that review materials (weeks-to-months). Formal response from the non-ORD panel.

15. Modeling was complex but clear dose response information across tumor types, species, genders etc.

16. RY – clarifying question – you used the epi study to see carcinogenicity but the dose response was animal studies?

a. WOE was combined epi and animal studies

b. RY – but you could do a potency study? But the animal tox studies (NTP) are very strong, so used this.

17. Follow-up on the NTP study, the epi work, and the IRIS Assessment summary (John)

18. Meeting on Wednesday the 28th – 5pm at 4th floor (we need to book a room). John can join by VTC. Bruce is joining the meeting. Nancy to join as well. Update the invitation on his calendar. Also need to let attendees know who to call for security etc.

19. Pull the public comments as well as the Nancy comments on Chloroprene (Tina to reach out to Nancy)

20. Let OAQPS and Region 6 be aware of the meeting (John)

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